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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,450	04/13/2001	John McMichael	13024/37276	2932

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/834,450	MCMICHAEL, JOHN	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *10/27/03*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment and remarks, filed 10/27/03, are acknowledged.

2. Claims 1-8 and 10-12 are pending and being acted upon.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless --.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 5-8, and 11 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Posselt et al. (1990), for the reasons set forth in the paper mailed 9/04/03.

Applicant's arguments, filed 10/27/03, have been fully considered but are not found persuasive. Applicant argues "The anticipation rejection over Posselt should be withdrawn in light of the amendment of independent claim 1, from which all remaining claims depend, to specify that method of administering an effective amount of an antigenic preparation presenting antigens characteristic of the allograft to the recipient is carried out in the absence of generalized immunosuppressive therapy. This is contrary to the practice and teaching of Posselt which discloses the use of generalized immunosuppressive therapy by the administration of rabbit antiserum to rat lymphocytes (ALS) and/or the transplantation of the allograft to the thymus which it identified as "an immunologically privileged site."

Applicant is advised that the reference includes a teaching of a transplant absent any immunosuppressives, see for example page 1293, column 3, paragraph 2, wherein the reference discloses transplant to nonimmunosuppressed WF rats. Regarding the site of transplant, the claims recite no limitations regarding where the transplant may occur, thus transplant to the thymus comprises prior art to the method of the instant claims.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior

> art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 3, 4, 10, and 12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Posselt et al. (1990), for the reasons set forth in the paper mailed 9/04/03.

Applicant's arguments, filed 10/27/03, have been fully considered but are not found persuasive. Applicant argues that transplant to an immunologically privileged site, as set forth in the reference, teaches away from the invention of the instant claims.

It is the Examiner's position that the instant claims recite no limitation excluding transplant to an immunologically privileged site, thus the method of the prior art is the method of the instant claims.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-8, and 10-12 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons set forth in the paper mailed 9/04/03.

Applicant's arguments, filed 10/27/03, have been fully considered but are not found persuasive. Applicant argues that "the specification teaches at page 3, lines 18-24 that preferred antigenic preparations comprise donor tissue which has been mechanically homogenized. The specification further teaches that antigens from sources other than donor tissue may be used which are combined to "replicate the antigenicity of the donor tissue." (page 3, line 24)."

It is the Examiner's position that this citation comprises an insufficient definition of "antigens characteristic of the allograft".

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-8 and 10-12 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons set forth in the paper mailed 9/04/03.

Applicant's arguments, filed 10/27/03, have been fully considered but are not found persuasive. Applicant argues "The test for enablement is not that of perfection or of certainty but whether those of skill are enabled to practice the invention and whether a benefit (however imperfect) is provided by practice of the invention. In light of the severity of consequences that otherwise ordinarily occur with allograft rejections it is submitted that such a benefit is provided by the present invention and that accordingly, the rejection under 35 U.S.C. 112 (second paragraph) should be withdrawn."

First note that the rejection was under the first paragraph of 35 U.S.C. 112. That aside, it remains the Examiner's position that the specification provides a disclosure insufficient for one of skill in the art to practice the invention as claimed. Specifically, in at least some disclosed embodiments, the claimed method appears to kill more transplant recipients than benefits. Said killing would seem to be a compelling demonstration of a method that must be considered highly unpredictable.

11. No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire

on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805 The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Please Note: inquiries of a general nature or relating to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600

12/23/08
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER